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EXAMINER

SAVAGE, JASON L

ART UNIT	PAPER NUMBER
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1775

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/821,023

Applicant(s)

JIANG ET AL

Examiner

Jason L. Savage

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13,31 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 recites the component assembly containing no free nickel. The claim further recites that the filler material is... for bonding by brazing the stainless steel part to the titanium part. As stated by Applicant on page 4 in the first full paragraph of the response filed 6-13-07, 'it is also common knowledge that free nickel is not available post-brazing' (emphasis added). Applicant has failed to enable one skilled in the art to form an assembly comprising the recited material layers which contains no free nickel which has not been subjected to a post-brazing operation. Should Applicant mean that the claimed component assembly has been subjected to a post-brazing operation, the claim should positively recite that the assembly has been formed by brazing.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 1-12 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (US 6,722,002).

Chang teaches brazing strip filler materials comprising laminated foil layers which are suitable for use in bonding metal component parts consisting of Ti, Fe or Ni based alloys (col. 2, ln. 38-45 and col. 5, ln. 41-56). Chang further teaches a brazed component assembly comprising a 316 stainless steel metal part bonded to a composite filler material comprising two outer foil layers of nickel and an inner foil core layer of titanium (col. 6, ln. 52-57). Chang also teaches that titanium metal parts can be bonded to other metal parts by employing the brazing filler material to form a composite assembly (col. 6, ln. 65-67).

Chang does not exemplify an embodiment wherein a component assembly comprises a stainless steel part bonded to a titanium part via a filler layer comprising nickel and titanium foils. However, since Chang teaches bonding a titanium part with the filler comprising nickel and titanium layers (col. 6, ln. 58-64) and further teaches bonding a stainless steel part with a similar filler comprising nickel and titanium layers (col. 6, ln. 52-57); it would have been within the purview of one of ordinary skill in the art to have recognized that one could form a composite wherein a stainless steel part was bonded to a titanium part via the recited filler layer with a reasonable expectation of success. Absent a teaching of the criticality or showing of unexpected results from the claimed assembly composite, it does not provide a patentable distinction over the prior art.

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Regarding the limitation that the assembly be suitable for use in living tissue, since the assembly of Chang has the same structure and same materials as that claimed by Applicant, it would have been just as suitable for use in living tissue as that claimed by Applicant. Furthermore, the limitation that the assembly is suitable for use in living tissue is merely an intended use. Statements of intended use are not considered patentably distinguishing limitations. See Ex parte Masham 2 U.S.P.Q.2d 1647, 1648. In re Thuau 135 F.2d 344, 47 U.S.P.Q. 324. Application of Hack, 245 F.2d.246, 114 U.S.P.Q. 161.

Regarding the limitation in claim 1 that the filler material is "for bonding by brazing" the stainless steel part and titanium part, the claim limitation is drawn to an intended use. Statements of intended use are not considered patentably distinguishing limitations. Furthermore, Chang teaches that the multi-layer foil is used in brazing processes to join metal parts forming an assembly (col. 6, ln. 52-64). As such, Chang meets the intended use that the filler material would bond the metal parts by brazing.

Regarding the limitation in claim 1 that the assembly contain no free nickel, once the assembly of Chang is subjected to the recited brazing processes to join the metals parts forming the assembly, no free nickel would remain. The Patent and Trademark Office can require Applicant to prove that prior art products do not necessarily or inherently possess characteristics of claimed products where claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes; burden of proof is on Applicants where rejection based on inherency under 35 U.S.C. § 102 or on prima facie obviousness under 35 U.S.C. §

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103, jointly or alternatively, and Patent and Trademark Office's inability to manufacture products or to obtain and compare prior art products evidences fairness of this rejection, *In re Best, Bolton, and Shaw*, 195 U.S.P.Q. 431 (CCPA 1977).

Regarding claim 2, an assembly comprising the filler having two outer layers of nickel as described by Chang (col. 6, ln. 52-57) would meet the claim limitation of a nickel foil layer being adjacent to the titanium part.

Regarding claim 3, the Ni/Ti/Ni filler structure taught by Chang (col. 6, ln. 52-57) would meet the claim limitation.

Regarding claim 4, although Chang teaches the preferred placement of Ti layers in the brazing filler is somewhere in the middle layer; Chang clearly teaches that the constituents of the brazing alloys can be arranged in any sequence and that other arrangements other than the preferred arrangement with Ti in the middle may be useful in specific circumstances (col. 5, ln. 57-67). As such, it would have been obvious to one of ordinary skill in the art to have arranged the alloy layers in any sequence, including sequences wherein the outer layers were Ti wherein the specific arrangement of material layers would be determined by the specific circumstances in which the assembly were to be used. Absent a teaching of the criticality or showing of unexpected results, the claimed sequence of material layers does not provide a patentable distinction over the prior art.

Regarding claim 5, Chang teaches the stainless steel part is a 300 series stainless steel such as 316 (col. 6, ln. 52-57).

Regarding claims 6 and 8, although Chang is silent to the use of 316L stainless steel and Ti-6Al-4V, it would have been within the purview of one of ordinary skill in the art to have recognized that a wide variety of stainless steel and titanium alloys could be employed in the component assembly of Chang with a reasonable expectation of success. Absent a teaching of the criticality or showing of unexpected results from the use of the claimed alloys, they would merely be a design choice and thus do not provide a patentable distinction over the prior art.

Regarding claim 7, Chang teaches the titanium part may be a titanium alloy (col. 6, ln. 58-67).

Regarding claim 9, Chang teaches the filler reacts with and bonds to the metal parts (col. 6, ln. 6-14).

Regarding claim 10, Chang teaches the filler thickness of the nickel and titanium composite filler is typically 0.010 inches thick and that the thickness may be further reduced by cold rolling (col. 6, ln. 52-57). Chang further teaches that the brazing temperature is about 950°C (col. 7, ln. 1-5 and col. 8, ln. 7-19) which is less than the melting point of the titanium and stainless steel parts but greater than a melting point of the Ni-Ti eutectic formed from the filler material.

Regarding claims 11-12, the claims are drawn to article, not the method of making. Absent a teaching of the criticality or showing of unexpected results due to forming the filler foil layers by the claimed methods, they would not provide a patentable distinction over the prior art. Furthermore, it would have been obvious to have used

nickel and titanium foils formed by any known method for the filler in the assembly of Chang with a reasonable expectation of success.

Regarding claim 31, the laminated filler of Chang would facilitate brazing of the parts just as the filler claimed by Applicant.

Regarding claim 32, the limitation that said component assembly is capable of being bonded by a brazing process is drawn to an intended use. Statements of intended use are not considered patentably distinguishing limitations. The laminated filler of Chang would be suitable for use in a brazing process to form a bonded assembly comprising the components in the claimed component assembly.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (US 6,722,002) in view of Cusano et al. (US 3,994,430).

Chang teaches what is set forth above however it is silent to at least one of the filler layers being formed from metallic particulate. Cusano teaches a method of bonding metals to other metal substrates (col. 2, ln. 32-33). Cusano further teaches that a bonding agent may be used to bond the metal part to the other metal part and that the agent may be in particulate form (col. 3, ln. 20-30). Although it is recognized that Cusano teaches that the bonding is a direct bond wherein no intermediate layer of solder metal or the like is employed, Cusano is merely provided as a teaching that it is known in the art that bonding materials for bonding metal parts can be provided in particulate form. It would have been obvious to one of ordinary skill in the art to have recognized that bonding agents or layers such as the filler layers of Chang could be

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employed in a variety of forms including as layers comprising particulates with a reasonable expectation of success.

It is well settled that the test of obviousness is not whether the features of one reference can be bodily incorporated into the structure of another and proper inquiry should not be limited to the specific structure shown by the references, but should be into the concepts fairly contained therein, and the overriding question to be determined is whether those concepts would suggest to one of ordinary skill in the art the modifications called for by the claims, *In re Van Beckum*, 169 USPQ 47 (CCPA 1971), *In re Bozek*, 163 USPQ 545 (CCPA 1969); *In re Richman*, 165 USPQ 509 (CCPA 1970); *In re Henley*, 112 USPQ 56 (CCPA 1956); *In re Sneed*, 218 USPQ 385 (Fed. Cir. 1983).

In response to the issue whether the reference is nonanalogous art, it has been held that the determination that a reference is from a nonanalogous art is twofold. First, one decides if the reference is within the field of the inventor's endeavor. If it is not, one proceeds to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved, *In re Wood*, 202 USPQ 171, 174. In the instant case, both Chang and Cusano are generally drawn to bonding metal parts through the use of bonding assisting agents or materials.

Response to Arguments

Applicant's arguments filed 6-13-07 have been fully considered but they are not persuasive.

Claims 1-12 and 31-32 are rejected under 35 USC 103(a) as being unpatentable over Change (US Pat 6,722,002).

Applicant argues that the Examiner's finding of Chang teaching an assembly which is formed by brazing can only be correct if roll bonding is somehow construed to be brazing. While Chang does recite the use of roll bonding, the roll bonding steps are used to provide enough bond integrity to allow for cold reduction (col. 5, ln. 25-58). As is further recited by Chang, the cold reduction allows the formation of thicknesses of materials commonly used for brazing applications (col. 5, ln. 28-30). As such, it is clear that while intermediate roll bonding steps may be employed, the multilayer brazing strip fillers are to be used in a brazing process to form a composite assembly. Chang further exemplifies such a brazed composite assembly wherein an assembly is placed in a vacuum furnace for brazing (col. 6, ln. 52-60).

In addition thereto, Applicant has failed to positively recite that the component assembly has been subjected to brazing. As recited in the rejections above, the recitation of brazing in the claims is a statement of intended use which would not patentably distinguish the claims over the prior art. As further noted above, Chang teaches that the filler material and metal parts can be bonded by brazing (col. 6, ln. 58-64).

Applicant further argues that Chang does not teach or suggest any teaching of bonding Ti to stainless steel with a filler material. However, Chang teaches component materials to be joined by the composite filler are selected from a narrow set of materials such as Ti, Ni or Fe based alloys (col. 5, ln. 41-43). Chang further teaches that the use

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of a brazing filler that can be roll bonded provides advantageous properties when bonding component of dissimilar materials (col. 2, ln. 3-9). In light of the above teachings, one of ordinary skill in the art would readily envision each combination of materials and combination of dissimilar materials including the claimed combination of titanium and stainless steel parts.

Applicant asserts that Chang states the brazing alloys of his invention are used for bonding stainless to stainless or Ti to Ti with a sandwich that is wrapped in stainless as the 5-layer composite. As recited above, one of ordinary skill in the art would readily envision each combination of materials and combination of dissimilar materials including the claimed combination of titanium and stainless steel parts.

Applicant also states that Chang does not teach bonding a titanium part with the filler comprising nickel and titanium layers. As recited above, Chang teaches that the multilayer filler brazing strips may be used to braze components comprising or consisting of Ti (col. 5, ln. 40-56). As such, Applicant's argument that Chang does not teach bonding a titanium part with the filler comprising nickel and titanium layers is not persuasive.

Limitation to Use in Living Tissue

Applicant states that it is common knowledge that Ni is not implantable in living tissue. Applicant further states that it is also common knowledge that free nickel is not available post-brazing, in start[sic] contrast to the product of roll-bonding. As recited in the rejection above since the assembly of Chang has the same structure and same

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materials as that claimed by Applicant, it would have been just as suitable for use in living tissue as that claimed by Applicant. Furthermore, the limitation that the assembly is suitable for use in living tissue is merely an intended use. Statements of intended use are not considered patentably distinguishing limitations.

Regarding the limitation that the assembly contain no free nickel, once the assembly of Chang is subjected to the recited brazing processes to join the metals parts forming the assembly, no free nickel would remain.

Declaration of Guangqiang Jiang, Ph. D.

The Declaration of Dr. Jiang has been reviewed and considered. The Declaration recites that titanium is never directly bonded to stainless steel with a composite braze foil between them in section 3). As recited in the rejection above, one of ordinary skill in the art would readily envision each combination of materials and combination of dissimilar materials including the claimed combination of titanium and stainless steel parts.

Dr. Jiang further adds that he would seriously doubt that Chang's bonding technique will work as it is taught which presumably is in reference to the embodiment Dr. Jiang describes in Figure 1. Dr. Jiang asserts that Chang teaches that the Ni/Ti/Ni filler is first bonded to stainless steel on each surface of the filler and subsequently has Beta-21 Ti layers bonded to the stainless steel surfaces.

There appears to some misunderstanding between Applicants and that of the Examiner in the interpretation of the teaching of Chang due to some confusing language

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in column 6, lines 52-64. While Chang recites 'the resulting five layer composites' in line 58 directly following the disclosure of the Ni/Ti/Ni composite bonded to a stainless steel, it is the position of the Examiner that Chang was referencing the five layer composites such as the Cu/Ni/Ti/Ni/Cu composite recited in col. 6, ln. 23-28 and not to the embodiment having stainless steel recited in lines 52-57. The teaching by Chang that the 'resulting braze joint can be cross-sectioned and metallurgically shown to be sound between the Beta-21 alloys' (col. 6, ln. 62-64) would appear to further support this interpretation.

Dr. Jiang further states that when the resulting five layer composite(s) is placed between two sheets of Beta-21 Ti, the Ni/Ti/Ni brazing alloy does not contact the stainless steel sheets. This argument is not persuasive since Chang clearly teaches the Ni/Ti/Ni brazing alloy contacts a stainless steel sheet (col. 6, ln. 52-57). Should Dr. Jiang have intended to state that Ni/Ti/Ni does not contact the Beta-21 Ti sheets, it is the position of the Examiner that the Ni/Ti/Ni composite would fall within 'other variations of the multilayer composites' which can be bonded to the Ti sheets.

Dr. Jiang also states that if Chang is deemed to be referring to stainless steel when he mentions that 'brazing alloys according to this invention are useful for brazing components comprising or consisting of Ti, Ni, or Fe based alloys' [col. 5, lines 41-43], the the preceding description is his teaching of Fe based alloy bonding. It is unclear what Dr. Jiang intends by this, however the Examiner would agree that the Ni/Ti/Ni filler bonded to a stainless steel would be a brazing alloy (Ni/Ti/Ni) which is useful for brazing an Fe based component (stainless steel) as taught by Chang.

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Dr. Jiang further states that in start[sic] contrast to Applicant's invention, it does not involve the roll-bonded composite reacting with or contacting the Beta-21 Ti sheet. This argument is not persuasive since the roll-bonded composite would be a multilayer filler material of nickel and titanium foils and the Beta-21 Ti would be a titanium part as required by the claim limitations.

Regarding the embodiment presented schematically in Figure 2, once again there appears to be a misinterpretation by Applicant. The 'five layer composites' are the multilayer filler brazing strips such as disclosed in col. 6, ln. 24. As such, the embodiment disclosed at the bottom of col. 6, line 65 – col. 7, ln. 5 would be a 7 layer assembly comprising Beta-21 Ti/Cu/Ni/Ti/Ni/Cu/Beta-21 Ti wherein the center portion is the 'five layer composite'.

In summary, it has been noted that Applicant appears to be focused on the two or three embodiments disclosed at the bottom of column 6 in Chang. The Examiner has attempted to clarify how the teachings of Chang have been interpreted in light of Applicant's arguments based on those embodiments. However, the Examiner would like to also stress that the disclosure of Chang is not limited to any single embodiment or only those specific examples disclosed and that all of the disclosures in a reference must be evaluated for what they fairly teach one of ordinary skill in the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason L. Savage whose telephone number is 571-272-1542. The examiner can normally be reached on M-F 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on 571-272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jason Savage
8-15-07



JENNIFER C. MCNEIL
SUPERVISORY PATENT EXAMINER

8/20/7